

August 10, 2016



U.S. Department
of Transportation

East Building, PHH-30
1200 New Jersey Avenue S.E.
Washington, D.C. 20590

**Pipeline and Hazardous
Materials Safety Administration**

DOT-SP 20250

EXPIRATION DATE: 2018-04-30

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Eli Lilly and Company
Indianapolis, IN
2. PURPOSE AND LIMITATION:
 - a. This special permit authorizes the one-time transportation in commerce of certain infectious substances in special packagings (freezers). This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein.
 - b. The safety analyses performed in the development of this special permit only considered the hazards and risks associated with the transportation in commerce.
 - c. No party status will be granted to this special permit.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR §§ 173.196(a) and 173.199(a) in that alternate packagings are authorized as specified herein.
5. BASIS: This special permit is based on the application of Eli Lilly and Company dated May 10, 2016, submitted in accordance with § 107.117 and a determination that it is necessary to protect life and property.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identi- fication Number	Packing Group
Infectious substances, affecting animals only	6.2	UN2900	N/A
Infectious substances, affecting humans	6.2	UN2814	N/A
Biological substance, Category B	6.2	UN3373	N/A

7. SAFETY CONTROL MEASURES:a. PACKAGING -(1) PACKAGING METHOD A -

(i) INNER PACKAGING - Leakproof cryovials (primary receptacles) with a capacity of not more than 5 ml must be capped and placed in a cardboard box with water resistant coating containing not more than seventy two (72) primary receptacles. Multiple primary receptacles placed in the cardboard box must be either wrapped individually or separated to prevent contact between them.

(ii) The boxes are loaded into racks in the freezers. Any open space between the boxes must be filled so the materials cannot shift around.

(iii) In one freezer, three (3) individual boxes not in racks, containing one hundred (100) 15 ml tubes, one hundred seven (107) 50 ml tubes, and one (1) 10 ml tube.

(iv) In one freezer, lying loose, two (2) 500 ml bottles in bags, not boxes, eight (8) 850 cm² roller bottles, forty-five to fifty (45 - 50) 500 ml bottles, one (1) 100 ml bottle. 45 (forty-five) 15 ml tubes in tube racks. An additional

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five (5) boxes containing varying amounts of 50 ml tubes.

(v) OUTER PACKAGING - Four (4) -80°C freezers with two sets of insulated doors. The outer insulated door must be padlocked closed.

(2) PACKAGING METHOD B -

(i) INNER PACKAGING - Leakproof cryovials (primary receptacles) with a capacity of not more than 1.5 mL must be capped and placed in a cardboard box with water resistant coating containing not more than thirty-six (36) primary receptacles. Multiple primary receptacles placed in the cardboard box must be either wrapped individually or separated to prevent contact between them.

(ii) The boxes are loaded into racks which are placed in the freezers. Any open space between the boxes must be filled so the materials cannot shift around.

(iii) OUTER PACKAGING - Two (2) Louis nitrogen freezers, cryogenic vessel containing liquid nitrogen. The lids must be padlocked closed.

b. OPERATIONAL CONTROLS -

(1) This special permit authorizes the transportation of six packages, four -80 °C freezers and two Louis nitrogen freezers, containing infectious substances using a specialized transport vehicle(s) under exclusive use from Indianapolis, IN to Greenfield, IN.

(2) A specialized dedicated transport vehicle must be used to transport packages containing infectious substances.

(3) All freezers must be secured against movement in the transport vehicle, and strapped around the doors to keep them closed.

(4) An itemized list of contents must be secured to the outside of each freezer.

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(5) The temperature of the freezer must be monitored during the transit. The infectious substances in the freezer must be kept frozen at all times at the operating temperature range between -80 °C and -30 °C. The transport vehicle must be equipped with an environmental control system as a backup capable of turning on power to maintain a temperature at -30 °C or below in case of accidental loss of temperature control in the freezer.

(6) Emergency refrigeration and response equipment and procedures must be in place and operational to address loss of refrigeration, delay in transportation or release of an infectious substance.

8. SPECIAL PROVISIONS:

- a. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.
- b. Each outer packaging (freezer) must be marked "DOT-SP 20250" in accordance with § 172.302(c).

9. MODES OF TRANSPORTATION AUTHORIZED: Motor Vehicle.

10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each motor vehicle used to transport packages covered by this special permit.

11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:

- o All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
- o Persons operating under the terms of this special permit must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
- o Registration required by § 107.601 et seq., when applicable.

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Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this special permit, including display of its number, when this special permit has expired or is otherwise no longer in effect.

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU)—"The Hazardous Materials Safety and Security Reauthorization Act of 2005" (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term "exemption" to "special permit" and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:



for William Schoonover
Acting Associate Administrator for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Material Safety Administration, U.S. Department of Transportation, East Building PHH-30, 1200 New Jersey Avenue, Southeast, Washington, D.C. 20590.

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Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm. Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: kah